### 00:00:56,858

My name is Rodney Wallace and I'm director of BARDA's detection, diagnostics and devices infrastructure division. DDDI develops diagnostics to address BARDA's entire portfolio of medical countermeasures. For CBRN division, we support bio dosimetry diagnostics, biothreat diagnostics, anti-microbial resistance diagnostics.

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For influenza and emerging infectious disease divisions, we develop influenza diagnostics, diagnostics for emerging diseases, such as COVID, Zika, Ebola, ventilators and respiratory protection devices. Some of our key strategies in DDDI are home testing, it's been a tremendously important capability during COVID-19 response, point of care diagnostics and of late we've been expanding manufacturing capacity at domestic diagnostics manufacturers.

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DDDI has funded 15 diagnostic tests that have achieved either FDA 510K clearance or approvals. For public health emergency response, we received the EUAs for two Ebola diagnostics that are still used today to contain the Ebola outbreak in West Africa.

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We received two INDs for blood screen test for Zika and four EUAS for diagnostics for Zika. All of these tests today have achieved 510K clearances or approvals. For the COVID-19 response, we first focused on molecular diagnostic tests because they were the most sensitive and the fastest to develop.

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We've achieved 14 EUAs so far for molecular tests. We then expanded into antigen diagnostic tests, receiving five EUAs for antigen tests so far. We developed or funded the development of antibody tests, receiving seven EUAs so far. We've also, as I mentioned earlier, expanded domestic manufacturing capacity at six sites in the United States.

## 00:03:16,988

hows BARDA's portfolio of diagnostic products. And these are pictures of the platforms that the diagnostics have performed on. First of all, we covered all three technology space mentioned earlier, we have molecular diagnostics, antigen diagnostics and antibody diagnostics, but we also covered the gambit of use cases.

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Everything from extremely high put molecular labs to smaller molecular labs that are needed in rural communities, to point of care tests for people to get testing done at their doctor's offices, and the home use tests, which as I mentioned earlier, have become extremely important. during the COVID-19 outbreak.

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In the near term, DDDI will continue focusing on our COVID-19 diagnostics, and our existing CBRN and Flu programs. In the medium term, we are going to take many of those COVID 19 diagnostic programs that achieve the UAE and fund them all the way through their 510K clearance. We're going to continue executing on our existing manufacturing capacity expansion programs. And we're going to focus on establishing a much faster contracting mechanism to allow us to respond even faster to the next public health emergency.

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Longer term, we're gonna be focusing on threat diagnostics and tools to speed up the development of an antigen and antibody and protein tests so that we can have those available quicker in the next public health emergency.

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I'd like to thank all of the BARDA staff and our contractors that work tirelessly to respond to the COVID-19 pandemic. I also hope many of you will be able to join us on day two of this year, where DDDI we'll go into much more detail into many of these programs.